

Jan-14-2000 11:38am From-PILLSBU ADISON

T-871 P.002/004 F-007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of
BRANSTROM et al.

Appln. No. 08/711,961

Group Art Unit: 1636

Filed: September 6, 1996

Examiner: J. Railey

Title: BACTERIAL DELIVERY SYSTEM

* * * *

DECLARATION UNDER RULE 131

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231



Sir:

I, Donata Sizemore, do hereby declare and state:

1. I am an inventor on Patent Application No. 08/711,961, and I am familiar with the specification and prosecution history, including the Office Action issued July 19, 1999.

2. In the July 19, 1999 Office Action, the Examiner rejected pending claims 45-55 as being anticipated by U.S. Patent No. 5,877,159 issued to Powell et al. on March 2, 1999. The Examiner indicated that the Powell et al. patent has a priority date of May 3, 1995.

3. The invention described and claimed in Application No. 08/711,961 was made prior to May 3, 1995, as evidenced by the facts set forth on page 1 of the July 1995 invention disclosure submitted by myself and my coinventors to the United States Department of the Army, assignee of the invention, a copy of which is attached hereto.

4. The information set forth on the attached page is a

Jan-14-2000 11:38am From-PILLSBURG ADISON

T-871 P-003/004 F-987

BRANSTROM et al. -- Appln. No. 08/711,961

true representation of the facts surrounding the invention to the best of my belief and knowledge.

5. I declare further that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent specification or any patent issuing thereon.

By Danah N. Lymer

Date 1/14/00



Jan-14-2000 11:39am

From-PILLSBURY



UNITED STATES OF AMERICA

INVENTION DISCLOSURE

(THIS FORM AND ACCOMPANYING DRAWING AND DESCRIPTION SHEETS ARE TO BE COMPLETED FOR EACH INVENTION PROMPTLY FORWARDED TO THE PATENT ACTIVITIES)

T-871 P-004/004 F-887

PATENT ACTIVITIES

DOCKET NO.

ASSIGNED TO:

SHORT TITLE OF INVENTION: Immunizations and for a potential vaccine candidate against *Shigella flexneri* infection.

FULL NAME(S) OF INVENTOR(S) (FIRST) (MIDDLE INITIAL) (LAST) HOME ADDRESS(ES) (CITY) TEL. NO. AREA CODE

(1) Arthur A. Branstrom 309 Cedar Lane, Rockville MD 20851 (202)782-3013

(2) Donald R. Sizemore 10005 Steadwick Rd. #301, Gaithersburg MD 20879 (202)782-3013

(3) James C. Sargent 1622 Kalmia Rd. NW, Washington DC 20012 (610)277-4639

INFORMATION AND DATES CONCERNING THIS INVENTION

NEEDED IN THE EVENT OF A CONTEST OF PRIORITY OF INVENTION IN THE U.S. PATENT AND TRADE-MARK OFFICE. ALL RECORDS CITED SHOULD BE DATED AND SIGNED BY TWO INDEPENDENT WITNESSES WHO HAVE READ AND UNDERSTOOD THE MATERIAL.

ON WHAT DATE DID YOU FIRST THINK OF THIS INVENTION (WHAT RECORDS SHOW THIS?)

(1) Primers for *asd* deletion were designed and synthesized 08/12/93.

GIVE DATE OF AND IDENTIFY EARLIEST SKETCH OR DRAWING

(2) Freezer stock of constructed suicide vector for chromosomal mutagenesis of *asd* made 01/19/94. The mutated *S. flexneri* was made and officially documented 09/19/94. Laboratory Notebook #A0620.

WHEN/WHERE AND TO WHOM DID YOU MAKE THE FIRST DISCLOSURE TO OTHERS OF THE INVENTION EITHER ORALLY OR IN WRITING?

(3) June, 1993/Palo Alto. Orally and in writing (under confidentiality) to Dr. Nelson Teng.

DESCRIBE DETAILS OF ANY WORK OR TESTS DONE TO PRODUCE OR OPERATE THE INVENTION GIVE DATES AND WITNESSES (USE OTHER PAGES IF NECESSARY)

(4) See attached documentation for item 14A (Drawing and Description Sheet)

DESCRIBE AND GIVE DATES OF ANY OTHER SKETCHES, DRAWINGS OR REPORTS PERTINENT TO THIS INVENTION

(5) June 1993, at Palo Alto, discussed in confidence with Dr. Nelson Teng.

USE, SALE OR PUBLICATION

NEEDED TO ESTABLISH THE DATE OF ANY PRINTED PUBLICATION, PUBLIC USE OR SALE, SINCE NO PATENT APPLICATION MAY BE FILED AFTER ONE YEAR FROM SUCH DATE.

IF INVENTION HAS BEEN SOLD OR USED FOR PROFIT - WHEN AND TO WHOM DISCLOSED OR WHEN AND HOW USED?

(6) N/A

HAS A DESCRIPTION OF THIS INVENTION BEEN MADE AVAILABLE TO PERSONS OUTSIDE THE AGENCY (WRITTEN OR ORALLY) IF SO, HOW AND WHEN AND WAS USE RESTRICTED?

(7) Yes: Submitted for review for publication on June 7, 1995.
Access made available to Dr. David Hone for purpose of collaboration.

POTENTIAL MARKET INFORMATION

NEEDED FOR POSSIBLE MARKET-ING INVESTIGATIONS AND AS AN AID TO POTENTIAL LICENSING TO OTHERS.

DESCRIBE ANY POTENTIAL OR EXISTING MARKET FOR SALE OR LICENSE OF THIS INVENTION

- A. GOVERNMENT: See attached for item #11 A and B.
- B. COMMERCIAL.
- C. IDENTIFY ANY KNOWN FIRMS OR VENDORS WHO MAY BE INTERESTED IN THE INVENTION

CONTRACT INFORMATION

A DETERMINATION OF RIGHTS IN THIS INVENTION WILL BE NECESSARY. (SEE AB 27-60)

IF THIS INVENTION WAS FIRST CONCEIVED OR CONSTRUCTED IN CONNECTION WITH:

- (12) A. MY DUTIES AS A GOVERNMENT EMPLOYEE
- B. MY WORK UNRELATED TO MY DUTIES AS A GOVERNMENT EMPLOYEE (PRIVATE, OFF DUTY ACTIVITIES)
- C. MY DUTIES AS A GOVERNMENT EMPLOYEE & WORKING WITH A CONTRACTOR
- D. NEITHER A, B OR C, EXPLAIN

Invention conceived outside of job description guidelines, but following the mission goal of vaccine development.

FOREIGN FILING CONSIDERATION

NEEDED TO DETERMINE THE POTENTIAL WORLDWIDE USE FOR THE INVENTION.

INDICATE THE POTENTIAL FOR USING THIS INVENTION IN FOREIGN COUNTRIES

- (13) ☐ POOR
- ☐ GOOD
- ☒ EXCELLENT

SECURITY CLASSIFICATION

PLEASE INDICATE THE SECURITY CLASSIFICATION IF KNOWN

- (13A) ☐ CLASSIFIED LEVEL
- ☐ UNCLASSIFIED
- ☐ CLASSIFICATION UNKNOWN

BEST AVAILABLE COPY